REMARKS

FORMAL MATTERS:

Claims 26, 28-29, 54-60, 66-68, 70-75 and 80-86 are pending and currently under examination after entry of the amendments set forth herein.

Claims 26, 28-29, 54-60, 66-68, 70-78 and 80-82 were rejected.

Claims 76, 77 and 78 are canceled herein as they are substantially duplicates of claims 67, 68 and 66 respectively.

Solely to expedite prosecution, Claims 26, 28-29, 54-60, 66, 71-75 and 80 are amended to even more clearly recite the present invention. In this regard, any amendments to the claims which have not been specifically noted as being made to overcome a rejection based upon the prior art, should be considered to have been intended to clarify the claims and not narrow the claims, such that no estoppel should be deemed to attach thereto.

Support for these amendments can be found throughout the application as originally filed and in the following exemplary locations: page 9, lines 17-20; page 11, lines 1-4; page 42, lines 3-17; and page 44, lines 10-20.

New claims 83-86 are added. Support for new claims 83-86 can be found throughout the application as originally filed and in the following exemplary locations: page 9, lines 17-20; page 11, lines 1-4; page 42, lines 3-17; page 44, lines 10-33; and FIG. 3.

No new matter is added.

REQUEST FOR EXAMINER INTERVIEW

Applicants respectfully request the courtesy of a telephone interview with the Examiner, once the Examiner has had an opportunity to review the current response. It is Applicants' hope that this interview will expedite prosecution by allowing an opportunity for Applicants to address with the Examiner any issues that may be outstanding following the filing of this response.

REJECTION UNDER 35 U.S.C. §103(a)

Claims 26, 28-29, 54-60, 66-68, 70-71, 75-78 and 80-82 were rejected under 35 U.S.C. §103(a) as allegedly being obvious over Manning et al. (WO 97/38698) ("Manning"). Applicants respectfully traverse the rejection as discussed below.

The Patent Office bears the burden of establishing a prima facie case of obviousness under 35 U.S.C. §103(a). *In re Fine*, 837 F.2d 1071, 1074 (Fed. Cir. 1988). In order to meet its burden, the Office must first demonstrate that the prior art teaches or suggests all the claimed limitations. See, *Pharmastem Therapeutics, Inc. v. Viacell, Inc.*, 491 F.3d 1342, 1360 (Fed. Cir. 2007), "the burden falls on the patent challenger to show by clear and convincing evidence that a person of ordinary skill in the art would have had reason to attempt to make the composition or device, or carry out the claimed process, and would have had a reasonable expectation of success in doing so."

In addition, the Supreme Court in *KSR* emphasized that consideration of prior art that teaches away from the claimed invention is also relevant to the determination of obviousness. The Court stated that "when the prior art teaches away from combining certain known elements, discovery of a successful means of combining them is more likely to be nonobvious." *KSR Int'l Co. v. Teleflex Inc.*, 127 S. Ct. 1727, 1740 (2007) (citing *United States v. Adams*, 383 U.S. 39, 40). See also, *Dystar Textilfarben GmbH v. C.H. Patrick Co.*, wherein the Federal Circuit stated that "[once] all claim limitations are found in a number of prior art references, the factfinder must determine '[w]hat the prior art teaches, whether it teaches away from the claimed invention, and whether it motivates a combination of teachings from different references.'" *Dystar Textilfarben GmbH v. C.H. Patrick Co.*, 464 80 U.S.P.Q.2d 1641, 1646 (Fed. Cir. 2006), *citing In re Fulton*, 391 F.3d 1195, 1199-1200 (Fed. Cir. 2004).

Finally, as recognized by the Office in the MPEP §2143.01, "[i]f [the] proposed modification would render the prior art invention being modified unsatisfactory for its intended purpose, then there is no suggestion or motivation to make the proposed modification." The Federal Circuit stated a similar principle in *In re Gordon*, indicating that where the proposed modification would render the prior art invention unsatisfactory for its intended purpose, the prior art invention effectively teaches away from the proposed modification. *In re Gordon*, 733 F.2d 900, 902 (Fed. Cir. 1984)

As currently amended, Claim 71, the sole independent claim, recites:

A method for delivering a therapeutic agent into the inner ear of a living subject, said method comprising:

providing a drug delivery unit comprising a carrier material and a therapeutic agent combined therewith, wherein said carrier material provides for controlled release of the therapeutic agent from said drug delivery unit over time, and further wherein

*said drug delivery unit is configured as a pellet, disk, tablet, plate, sphere, cube, cylindrical unit, strand, or plug**, and***

***said drug delivery unit is shaped and sized for partial or complete insertion into the round window niche of the subject**; and*

inserting said drug delivery unit directly into the round window niche of the subject such that said unit is positioned either partially or completely within the round window niche, wherein the therapeutic agent is released from the drug delivery unit, contacts the round window membrane and passes into the inner ear.

Applicants respectfully submit that Manning fails to teach or suggest at least the following elements of claim 71:

- ***"providing a drug delivery unit . . . wherein said drug delivery unit is configured as a pellet, disk, tablet, plate, sphere, cube, cylindrical unit, strand, or plug",***
- ***"said drug delivery unit is shaped and sized for partial or complete insertion into the round window niche of the subject", and***
- ***"inserting said drug delivery unit directly into the round window niche of the subject such that said unit is positioned either partially or completely within the round window niche"***

First, Manning clearly fails to provide any teaching or suggestion with respect to a drug delivery unit "***configured as a pellet, disk, tablet, plate, sphere, cube, cylindrical unit, strand, or plug"*** as presently claimed. In fact, Manning's disclosure teaches away from a drug delivery unit having such a structure. This is because Manning teaches a fluid composition lacking a structure such that "**[t]he composition is fluid enough to be injected through a fine gauge needle (as small as 26 gauge).**" Manning at page 5, lines 24-25. See, also, Manning at page 10, lines 21-23, indicating that **"[t]he composition is always somewhat fluid, unlike solid implants or microspheres or other controlled release dosage forms**." This disclosure of Manning directs a person of ordinary skill in the art away from a drug delivery unit having a structure, such as those set forth in claim 71, in favor of a

composition of such fluidity that the composition may be injected through a fine gauge needle. Manning teaches that such fluidity assures proper placement of the composition. See, Manning at page 5, line 25.

The Office apparently proposes a modification of the composition of Manning which would result in Manning's fluid composition having one or more of the structures set forth in claim 71. However, Applicants submit that such a modification would render the composition of Manning unsatisfactory for its intended purpose because it would no longer be "fluid enough to be injected through a fine gauge needle" and accordingly Manning's goal of assuring proper placement via injection of a fluid composition would be thwarted. Thus, in accordance with the law as set forth in *In re Gordon*, Manning effectively teaches away from the proposed modification.

Second, the pending claims have been amended to explicitly recite that "***said drug delivery unit is shaped and sized for partial or complete insertion into the round window niche of the subject***". There is simply no such teaching or suggestion in Manning. Specifically, the only description provided by Manning with respect to the structure of its dosage form is a characterization of the dosage form as a fluid, which lacks a defined structure, such that it is capable of being injected through a fine gauge needle. Accordingly, Manning fails to teach or suggest a drug delivery unit **shaped and sized** for partial or complete insertion into the round window niche of the subject.

Third, Manning fails to teach or suggest "***inserting said drug delivery unit directly into the round window niche of the subject such that said unit is positioned either partially or completely within the round window niche.***" Manning merely discloses injection or pumping of its fluid dosage form "behind the ear drum" to the middle ear. See, e.g., Manning at page 5, lines 20-23. While such injection may result in some amount of the dosage form eventually reaching the round window niche, it does not amount to a teaching or suggestion to insert a drug delivery unit as explicitly claimed in the instant application, i.e., ***directly into the round window niche of the subject***. As discussed in the instant specification, placement of the drug delivery unit directly into the round window niche can provide several advantages over a more generalized delivery, e.g., avoiding premature drug delivery and inadvertent delivery to other tissue regions outside the round window niche. See, e.g., page 21, line 32 – page 22, line 4 of the instant application as filed.

With specific reference to claim 70, Applicants note that the Office has failed to demonstrate that Manning teaches or suggests a method as claimed in claim 71, which includes the additional limitation of claim 70, "***wherein release of the therapeutic agent from the drug delivery unit is without inadvertent delivery to other tissue regions outside the round window niche***." As discussed above, Manning teaches injection or pumping of a fluid dosage form "behind the ear drum" to the middle ear. If anything, the teachings of Manning suggest that inadvertent delivery to tissue regions outside the round window niche would be likely because of the fluid nature of the dosage form and the fact that Manning does not teach inserting a drug delivery unit directly into the round window niche of the subject. Accordingly, Manning neither teaches nor suggests a method "***wherein release of the therapeutic agent from the drug delivery unit is without inadvertent delivery to other tissue regions outside the round window niche***."

In view of the above, Applicants submit that the Office has failed to establish a *prima facie* case of obviousness under 35 U.S.C. §103(a) over Manning. Reconsideration and withdrawal of the rejection are respectfully requested.

Claims 72-74 were rejected under 35 U.S.C. §103(a) as allegedly being obvious over Manning in view of Peterson (U.S. Patent No. 4,472,394) "Peterson". Applicants respectfully traverse the rejection as discussed below.

According to the Office, Manning teaches the invention substantially as claimed. The Office relies on Peterson solely for an alleged teaching of extended release of an active agent over a period of 60 days to 210 days. Office Action, page 5. The specific deficiencies in the Manning disclosure with respect to the claimed invention are set forth above. As Peterson's alleged teaching of extended release of an active agent over a period of 60 days to 210 days in no way cures the specific deficiencies present in Manning, the proposed combination of references fails to establish a *prima facie* case of obviousness for claims 72-74 which incorporate each of the limitations of independent claim 71.

CONCLUSION

Applicants submit that all of the claims are in condition for allowance, which action is requested. If the Examiner finds that a telephone conference would expedite the prosecution of this application, please telephone the undersigned at the number provided.

The Commissioner is hereby authorized to charge any underpayment of fees associated with this communication, including any necessary fees for extensions of time, or credit any overpayment to Deposit Account No. 50-0185, order number DURE-021.

Respectfully submitted,
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